

CDMRP: FOSTERING INNOVATION THROUGH PEER REVIEW

E. Melissa Kaime,* Katherine H. Moore,* and Steven F. Goldberg†

*Congressionally Directed Medical Research Programs, Fort Detrick, MD, USA

†Center for Peer Review and Science Management, SRA International, Frederick, MD, USA

The Congressionally Directed Medical Research Programs (CDMRP) is a collection of 18 individual programs that seek to find and fund the best research to eradicate diseases and support the warfighter for the benefit of the American public. In fulfilling its mission, CDMRP emphasizes innovative, high-risk, high-gain research that might otherwise not be funded and projects that forge new collaborations in furtherance of important research objectives. Research proposals (applications) are reviewed using a two-tiered process that includes peer review panels that evaluate scientific merit, innovation, and impact, followed by an external review that makes funding recommendations based on programmatic intent and portfolio balance. At both levels of review, CDMRP's processes are distinguished by the inclusion of consumer advocates, who are integral to the program's ability to focus on research that will have an impact on the communities affected by the relevant illness, injury, or disorder. Scientific peer review is executed using a dynamic and flexible process and produces a robust and comprehensive summary statement that serves as the basis for the second tier of review, informs subsequent award negotiations, and provides valuable feedback to all applicants. In combination with a strong commitment to integrity and transparency, CDMRP's peer review processes support the organization's mission to fund innovative, high-impact research.

Key words: Peer review; Innovation; Consumer involvement

INTRODUCTION

The Congressionally Directed Medical Research Programs (CDMRP), a research directorate within the U.S. Army Medical Research and Materiel Command (USAMRMC), was established in 1993 to manage congressional appropriations in support of disease-targeted extramural biomedical research. CDMRP is funded through the Department of Defense (DoD) by annual Congressional legislation known as the Defense Appropriations Act.

CDMRP is a collection of 18 individual programs that benefit the American public by seeking to find and fund the best research to eradicate diseases and support the warfighter. In fulfilling its mission, CDMRP emphasizes innovative, high-risk/high-gain research that might otherwise not be funded, and projects that forge new collaborations in furtherance of important research objectives.

These programs address a diverse array of topics, ranging from cancer (e.g., breast cancer, prostate cancer) to neurodegenerative disease (e.g., amyotrophic lateral sclerosis) to deployment-related medical conditions (e.g., psychological health and traumatic brain injury). Figure 1 depicts the growth and evolution of CDMRP since its inception, and shows the increasing diversity of the research managed by its programs.

Since its inception, CDMRP has maintained a central focus on innovation. This commitment to innovation is expressed both in its efforts to identify and fund transformative research and in the processes employed to evaluate proposals (applications) submitted for review. As a result, the scientific peer review process employed by CDMRP has several features that distinguish it from other grant-making entities.

Address correspondence to E. Melissa Kaime, M.D., Director, Congressionally Directed Medical Research Programs, 1077 Patchel Street, Fort Detrick, MD 21702, USA. Tel: 301-619-7071; Fax: 301-619-7796; E-mail: Melissa.kaime@us.army.mil

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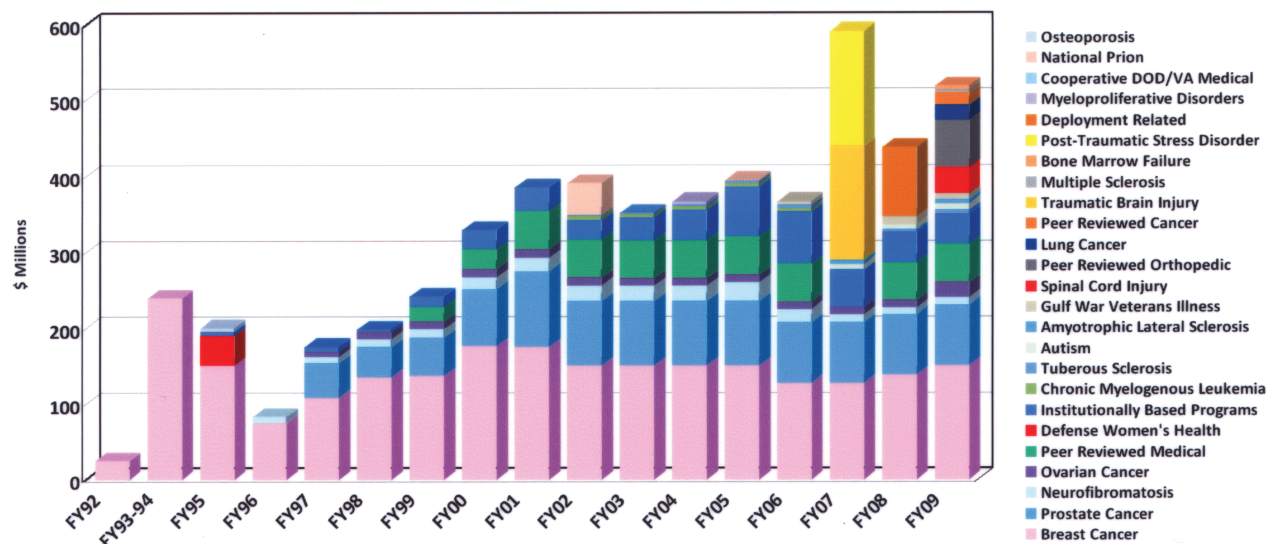


Figure 1. CDMRP funding history. To date the CDMRP has managed 94 separate research programs spanning cancer research, military-relevant research, and other disease-specific research. All of these programs are aimed at improving the health of all Americans. Since 1992, 68,175 proposals have been received and 9,675 have been funded.

UNIQUE ATTRIBUTES

To facilitate the execution of its mission and to ensure that funding decisions are made with a high degree of integrity and transparency, CDMRP has adopted a number of processes that, in combination, give rise to a unique approach to conducting application review.

TWO-TIER REVIEW

To evaluate competitive research proposals and to ensure both scientific excellence and programmatic relevance, CDMRP adopted the recommendations of the National Academy of Sciences Institute of Medicine (IOM) 1993 report *Strategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command* (1). This report recommended a two-tiered peer review system that could be tailored to accommodate the goals of each particular program. CDMRP has adhered to this approach to evaluate competitive proposals. For a proposal to be funded, it must be favorably reviewed by both tiers of the review system.

During the first tier of this review, *scientific peer review*, each proposal is assessed by discipline-specific panels for scientific merit and impact based

on the criteria set forth in the program announcements. These evaluations are captured through scores and written critiques, which are compiled into a summary statement. The second tier of review, *programmatic review*, uses a comparison-based process. Proposals are evaluated for their relevance to programmatic goals, alignment with identified research gaps, and contribution to portfolio balance. This level of review is conducted by each program's integration panel and uses the evaluations and scores provided by the scientific peer review panels to develop a list of funding recommendations, which are presented to the commanding general of USAMRMC for final approval (see Fig. 2 for an outline of the CDMRP funding process). Notably, the consideration of programmatic intent and portfolio balances means that proposals are not funded using an established "pay line" based on the scores assigned during the scientific review process.

CONSUMER ADVOCATE INVOLVEMENT

During the early 1990s, advocacy groups mobilized to lobby for research funding that would specifically address breast cancer, ultimately leading to the formation of the CDMRP Breast Cancer Research Program (BCRP) in 1993. Per the recom-

mendation of the 1993 IOM report, these advocacy groups were given representation on the BCRP Integration Panel and helped to set the strategic vision for this new program. Since the initiation of the BCRP, consumer advocates have been integrally involved in all CDMRP programs, serving both on the integration panel and (since 1995) on scientific peer review panels. Thus, consumer reviewers are involved at every stage of the funding cycle, and CDMRP was the first Federal funding agency to include laypersons on all peer review panels.

Consumer reviewers are members of the community affected by the illness or injury such as patients, survivors, caregivers, advocates, and family members. They play a major role in maintaining the focus of each program on disease-relevant research that has the potential to have a significant impact on the community affected. They represent the concerns and interests of their respective communities in the review process, provide a unique perspective on disease-related issues important to that community, and contribute a sense of urgency to the peer review process. Each consumer reviewer is nominated by an advocacy or support organization and is provided training on the peer review process.

Although consumer reviewers are full voting members of scientific peer review panels, they are

not expected to evaluate the proposed research strategy. Instead, these reviewers focus on the impact of the proposed project and frequently provide input on other review criteria to the extent they are comfortable doing so. Through their interactions with scientific reviewers serving on these same panels, these consumers provide valuable insight about the research being evaluated and its potential to result in a positive outcome for those affected by the disease, injury, or condition being addressed by that specific program.

ANNUAL PROGRAMMATIC GOAL SETTING

The funding and goals of the individual research programs managed by CDMRP are dependent on annual appropriations and targeted guidance made by Congress. Therefore, while some programs have received continuous funding for several years, there is no assurance from year to year that any individual research program will be able to solicit additional grant applications. As a result, each program is managed on an annual cycle and, once an award is made, funds are fully obligated for the duration of the period of performance.

Because of the variability of the congressional appropriations and restrictions on how and when funds may be spent, the CDMRP employs a flexi-

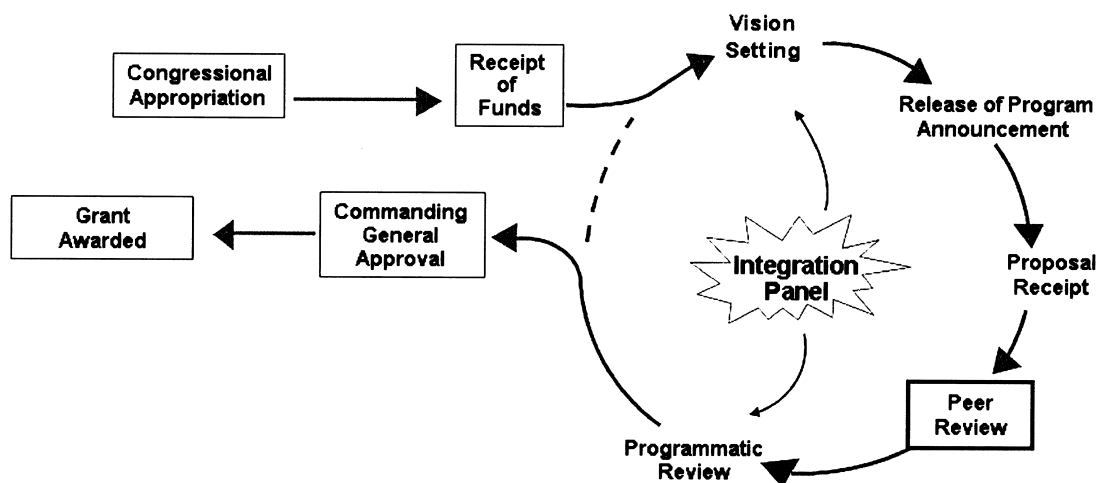


Figure 2. CDMRP funding cycle. Each program cycle begins with the Congressional appropriation. Each year the Integration panels develop a vision and funding mechanisms. Consumers are critical participants in Vision Setting, Peer Review, and Programmatic Review. All awards must be made within 2 years of the initial appropriation.

ble management cycle to maintain the individuality of each program while also meeting the needs of Congress, the DoD, the research and advocacy communities, and the public at large.

At the beginning of each program year, each integration panel will conduct a "Vision Setting" meeting, during which programmatic goals are evaluated and refined based on guidance received from Congress, recent advances in research and clinical treatment, and the position of the existing portfolio of funded research. Programmatic priorities are established to address identified gaps in knowledge, underfunded approaches for prevention, diagnosis, and treatment, and specific resource needs in that particular field. These priorities are, in turn, translated into an investment strategy in which available resources are allocated to specific focus areas and award mechanisms (which are selected, created, and/or refined to meet programmatic needs).

FOCUS ON INNOVATION

Consistent with its central philosophy of supporting innovation, CDMRP strives to stimulate new scientific knowledge by funding high-risk, high-gain research that would be less likely to be funded by other agencies. While an operative definition of innovation is difficult to articulate, many of the CDMRP programs emphasize the solicitation of transformative, paradigm-shifting research that represents more than an incremental advance in existing knowledge. In some award mechanisms, innovation is the most heavily weighted review criterion and given more consideration than research strategy. In addition to using innovation as a review criterion, CDMRP funds a number of smaller awards that permits the exploration of new, untested hypotheses; supports the creation of new collaborations and partnerships (which transcend institutional boundaries and subject matter areas); and seeks to develop future innovators and leaders in the field. One example of this focus on finding and funding untested ideas is the Concept award that was first offered in 1999. These one-page applications are reviewed by the two levels of peer and programmatic review without any identifiers for the applicant or their institution. Preliminary data

are not allowed in these one-page proposals. Since 1999, over 900 Concept awards have been selected for funding. The intended period of performance of these awards is 1 year. An outcome study was done on the Concept award mechanism in 2004, finding that approximately 72% of the projects met some or all of their goals, while only 15% reported that the goals of the project were not met. Almost two thirds of Concept awardees used findings from their BCRP concept awards in subsequent research applications.

PEER REVIEW PROCESS

The unique characteristics of CDMRP compel a dynamic and flexible approach to conducting scientific peer review. The programs within CDMRP share many common features, but each program is unique and largely autonomous. Although there are a number of award mechanisms that have been offered consistently, these are subject to change to meet the programmatic goals established by the integration panel during its vision setting process. Thus, the peer review process must be able to adapt to the introduction of new programs, changes to award mechanisms, and evolving review criteria, as well as to the high degree of interprogram variability.

The peer review process is tailored to meet the needs of each of these programs, while structured to maintain a high degree of consistency across programs and adherence to best practices to ensure the impartial assessment of scientific merit for all proposals submitted for consideration.

PEER REVIEW PANELS

Because of the annual funding appropriation to which CDMRP is subject, there are no standing panels or study sections. Instead, all peer review panels are assembled on an ad hoc basis, with the assigned scientific review officer responsible for recruiting a chairperson and a full panel of scientific reviewers (consumer reviewers are assigned by a consumer reviewer administrator). These panels are configured by program and review proposals that have been segregated by award mechanism

and subject matter area based on a dynamic mapping that varies by program and award mechanism. While applicants are asked to indicate primary and secondary research classification codes upon submission, they may not request assignment to a particular panel or suggest specific reviewers. These research classification codes are used to automatically assign proposals to peer review panels, with further adjustments made to ensure appropriate placement, to balance workload between panels, and to resolve potential conflicts of interest. The applicants do not know the composition or membership of the panel that their proposal is assigned to. At the end of each year's peer review cycle the names of the peer reviewers are released, but their panel assignment is not.

Because the review criteria for the various award mechanisms can be very different, a peer review panel generally reviews a single mechanism or a group of similar mechanisms (e.g., training award mechanisms). In so doing, panel members are able to retain their focus on the appropriate review criteria and the programmatic intent of a particular mechanism. In addition, this structure permits the design of special emphasis panels, which address such disparate topics as training awards, clinical trials, and health disparity research. The scientific areas covered in many such panels are broad; however, it is not uncommon that the number of proposals submitted for a single award mechanism is large enough to warrant multiple panels, each with a focused scientific area(s) and a comparable number of proposals.

PEER REVIEWERS

Since its inception, CDMRP has relied on more than 6,800 scientists and clinicians, as well as more than 1,000 consumers, for service as peer review panel participants. To achieve the highest quality of peer review, CDMRP solicits the participation of a diverse range of reviewers. The intention is to assemble peer review panels of individuals with a complementary blend of expertise, maturity, diversity, and viewpoints and to provide realistic workloads for the panel members. In general, 25% of panel members are first-time CDMRP reviewers, and limitations are imposed on reviewers returning

for multiple years; this reinforces the dynamic nature of the peer review panels.

Reviewers are selected based on their technical knowledge and disease-relevant experience as demonstrated by their funding history, professional experience, and publication record. In addition to members with expertise in the specific research topic, panels may have specialist reviewers such as biostatisticians, bioethicists, clinical trial managers, intellectual property experts, or academic deans, as appropriate to the particular award mechanism being reviewed. Specialist reviewers address specific aspects of the research and are often engaged for more complex award mechanisms such as clinical trials, research consortia, and therapeutic development awards.

PEER REVIEW PANEL MEETINGS

For most award mechanisms, peer review is conducted in multipanel on-site meetings. Depending on program size, all or most panels for a program may be reviewed at a single meeting, sometimes consisting of multiple consecutive sessions. This structure permits program staff the opportunity to orient all panel participants to the unique character of each program, helping to ensure a focus on the goals of the program and the intent of individual award mechanisms. Specific orientation sessions are generally held for scientific review officers and chairpersons, consumer reviewers, and new scientific reviewers. In addition, program history, goals, and unique features are highlighted during a plenary presentation immediately preceding the start of panel deliberations.

Developing Web-based and paperless review procedures (e.g., online proposal access and critique submission) allowed CDMRP to institute online reviews for certain mechanisms with comparatively small awards and abbreviated proposal formats, yielding the efficient and rapid evaluation of large numbers of proposals. Unlike on-site meetings, in which the full panel will discuss the merits of a proposal, for online reviews only those panel members assigned to the proposal will provide scores; however, in cases where the assigned reviewers provide disparate scores, an asynchronous

online discussion is initiated, moderated by the chairperson assigned to the panel. Subsequent to this discussion, the assigned reviewers have the opportunity to revise their scores and critiques.

PROPOSAL SCORING AND EVALUATION

Proposals are assigned for review by two or more scientist reviewers and a consumer reviewer, each of whom provides a written evaluation and preliminary scores based on the published review criteria. Scores are provided for each criterion using a 10 to 1 scale (with 10 being “outstanding” and 1 being “deficient”) (Table 1). The criteria scores form the basis for a global score using a 1.0 to 5.0 scale (with 1.0 being “outstanding” and 5.0 being “deficient”). Although no weighting is given for the individual review criteria, they are presented in order of decreasing importance. Reviewers are instructed to base their global score on the criteria scores, although unscored criteria (e.g., budget, proposal presentation, and others depending on the award mechanism) may be taken into consideration. Notably the scales used for the criteria and global scores are inversely (but nonlinearly) related; although there should be correspondence between the criteria scores and the global score, these scales are intended to discourage the calculation of a global score. All panel members score the proposal at the end of panel deliberations.

PREPROPOSAL REVIEW

An increasing volume of proposals, and the corresponding decrease in the percentage that were ul-

timately funded, suggested the need for a screening process to reduce the number of proposals brought forward for peer review. Therefore, for some award mechanisms, CDMRP requires the submission of a brief preproposal, which provides essential information about the intended proposal. After consideration of responsiveness to programmatic intent, apparent scientific merit, innovation, and/or impact, a subset of preproposal submitters are then invited to submit a full proposal. As a result, CDMRP is able to reduce costs by subjecting fewer proposals to a full peer review process and to reduce the burden on applicants who might otherwise spend time preparing a full proposal that would be unlikely to be funded.

EXPEDITED REVIEW

Another method used to increase the efficiency of the peer review process is expedited review, which is a form of triage used to reduce the number of proposals discussed during the peer review panel meeting. Expedited review recommendations are determined by program staff based on the preliminary (premeeting) scores provided by the assigned reviewers. Reviewers may not nominate a proposal for expedited review, but have the ability to “champion” any proposal, which will result in its being returned to the list of proposals to be discussed at the meeting.

The scores used to derive the expedited review list may include one or more criteria scores and/or the global score, as appropriate to the program and award mechanism. Thus, these decisions may be made on the basis of a proposal’s scores on innovation or impact rather than research strategy. Because funding decisions are not based solely on the final global score, a retrospective analysis of historical data is used to set the thresholds for expedited review (generally, between 10% and 25%) to minimize the probability that a potentially fundable proposal will be excluded from the discussion. Proposals subject to expedited review are not discussed during the peer review panel meeting and are not scored by the full panel; however, the principal investigator receives a summary statement.

Table 1. CDMRP Scoring Scale

Adjectival	Global	Criteria
Outstanding	1.0–1.5	10–9
Excellent	1.6–2.0	8–7
Good	2.1–2.5	6–5
Fair	2.6–3.5	4–3
Deficient	3.6–5.0	1–1

All grants receive Criteria scores for the individual review criteria (Innovation, Research Strategy, etc.) as well as an overall Global score. There is not a formula used to convert the Criteria score to a Global score. The two types of scores are related, but not derived from each other.

SUMMARY STATEMENTS

The output of the CDMRP peer review process is a robust and comprehensive summary statement that serves as the basis for the second tier of review, informs subsequent award negotiations, and provides valuable feedback to all applicants. A summary statement is prepared for every full proposal received and includes a summary of the panel's findings, global and criteria scores, the critiques provided by each reviewer (scientist, consumer, and specialist), and budget recommendations.

INTEGRITY AND TRANSPARENCY

CDMRP is committed to maintaining the transparency of its review process. A number of procedures are used to ensure the integrity of the review process.

COMPLIANCE REVIEW

A rigorous administrative compliance review is conducted for each proposal submitted to CDMRP to ensure that the specifications set forth in the program announcement have been followed and that no applicant has obtained a competitive advantage by virtue of a breach of these guidelines.

GOVERNMENT LIAISON

A government liaison (GL) is assigned to observe the deliberations of each peer review panel and is responsible for monitoring compliance with established processes and the conduct of an impartial and objective review of proposals. The GL is additionally responsible for ensuring that no panel member with a potential conflict of interest is present during deliberations.

CONFLICT OF INTEREST

Preventing conflicts of interest is critical for maintaining the integrity of the peer review process. Numerous procedures and detailed guidelines are established to identify and prevent potential conflicts, including both automatic and manual techniques.

CONFIDENTIALITY

Review procedures require that panel members treat all proposal materials, panel discussions, and review outcomes as confidential. Contact between applicants and a peer review panel member is prohibited, and the membership of individual peer review panels is not disclosed (although a list of all reviewers is published annually for each program).

INQUIRY REVIEW PROCESS

The Inquiry Review Panel (IRP) was established by CDMRP to address questions and appeals by applicants regarding either the scientific peer review or programmatic review of their proposals. The IRP determines whether factual or procedural errors have occurred and may recommend that a proposal be sent for rereview by either the scientific peer review or integration panels.

SUMMARY

In combination with a strong commitment to integrity and transparency, CDMRP's peer review processes support the organization's mission to fund innovative, high-impact research. CDMRP is a dynamic organization that must regularly adapt to changes in the amount and composition of its annual congressional appropriations, evolving programmatic visions, and a rapidly advancing scientific environment.

Unique attributes of CDMRP, such as consumer reviewer involvement and the use of a two-tier review process, ensure that the organization remains tightly focused on its mission. Despite the challenges posed by the fluid circumstances in which it operates, CDMRP is able to effectively and efficiently execute its mission through a commitment to rigorous process and its culture of continuous process improvement.

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ABOUT THE AUTHORS



Captain E. Melissa Kaime, M.D., FACP, completed a B.S. in Engineering from Vanderbilt University, graduating in 3 years with magna cum laude honors. She earned her M.D. from St. Louis University School of Medicine, and then completed her internship and internal medicine residency at the Naval Hospital, Oakland, CA, and a hematology/oncology fellowship at the Naval Medical Center San Diego. CAPT Kaime is a board-certified hematologist, oncologist, and internist who serves as the Director of the Congressionally Directed Medical Research Programs (CDMRP) Office, US Army Medical Research and Materiel Command. CDMRP ensures the sponsorship, and manages a research portfolio, of peer-reviewed meritorious science that meets the intent of Congressional interests.



Katherine H. Moore, Ph.D., received a B.S. and M.S. from the University of California, Davis. She earned her Ph.D. in Reproductive Physiology from Texas A&M University and completed postdoctoral fellowships at the University of Kentucky and the University of Texas M.D. Anderson Cancer Center. As a Science Officer in Grants Management at CDMRP, she has oversight of projects from the Breast Cancer Research Program.



Steven Goldberg, Ph.D., joined SRA International, Inc. in 2005, where he currently serves as Deputy Director for its Center for Peer Review and Science Management and as Project Director for scientific peer review services performed for the Congressionally Directed Medical Research Programs (CDMRP). Prior to joining SRA, Dr. Goldberg was a research fellow at the National Cancer Institute, and previously served as an executive in the financial services industry. He holds bachelor and master degrees in finance and a doctorate in cell and molecular biology, and is a certified Project Management Professional.

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